K031163

EXHIBIT 2

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JUL 0 8 2003

May 19, 2003

Contact: G.S. Pok, Managing Director

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: SEZ Safety Syringe
   Classification Name: Piston Syringe
   Common/Usual Name: Safety Syringe

2. Equivalent legally marketed device: EXEL Secure Touch Safety Syringe, K011754

3. Indications for Use (intended use) . This device is a safety hypodermic syringe for intramuscular and subcutaneous injection of medication to patients. This device aids in prevention of needlestick injuries.

4. Description of the Device: SEZ Safety Syringe consists of 1) a calibrated hollow barrel which contains medication and, after use, confines 2) the needle, 3) a movable plunger which aspirates medication and, after injection, retracts the needle into the barrel, At the distal end of the barrel, there is a female connector(nozzle) for fitting 3) a male connector(hub) to which the needle is firmly attached by bonding material. The needle is securely protected by 5) a cap before use. For sealing purpose, 6) an o-ring, between barrel and hub, and a gasket, between barrel and plunger, are used. The function of the device is to deliver medication and, after injection, to destroy the needle in the barrel to prevent needlestick injury and possible reuse. The injection process is practically the same as that of the conventional, non-safety, syringes, that is, to aspirate medication from a vial and to deliver it to a patient. The disposal process is turn-pull-push operation, each step of which is clearly and unmistakably defined. By turning the knob of the plunger half round clockwise, hub is disassembled from the barrel. Then plunger is pulled backward until it stops, which retracts hub and needle into the barrel. Needle is tilted to one-side pushed by the rod at plunger head. Finally, the plunger is pushed forward to crumble the needle in the barrel. Needle and contaminated fluid are contained in the barrel safely and used syringe can be discarded in the sharps container..

5. Safety and Effectiveness, comparison to predicate device:

Device name	Predicate syringe EXEL Secure Touch Safety Syringe (K011754)	SEZ safety syringe
Intended Use	This device is a safety hypodermic syringe for injection of medication to patients. This device aids in prevention of needlestick injuries.	Identical
Principle of operation	Activation of safety feature consists of two steps: 1) Disassemble needle assembly from the barrel by turning the plunger.	Identical
	2) Retract needle into barrel and confine it in the barrel by pulling the plunger backward. To guarantee confinement of needle, break the plunger before disposal.	Identical, except that needle confinement is guaranteed by pushing the plunger forward before disposal.
Volume (ml/cc)	3 and 5 combined	3
Nozzle type	Male conical lock fitting with rotatable internally threaded collar	Female conical lock fitting with rotatable internally threaded neck
Barrel marking	- Scale : conforms to ISO 7886-1:1993(E)	Identical
Reuse	Non-reusable	Identical
Biocompatibility	Conforms to ISO 10993-1	Identical
Materials	1) Plastic parts : polypropylene (homo type) 2) Gasket : thermoplastic rubber 3) O-ring : nitrile rubber 4) Packing film : Medipeel film 5) Packing paper : Ethypel paper	Identical Identical Identical Identical Identical
Sterility	Sterilized by ethylene oxide gas SAL=10^{-6}	Identical

6. Conclusion: In all material respects, the SEZ Safety Syringed is substantially equivalent to the predicate device. The conclusion is based on biocompatibility testing, clinical testing, compliance with voluntary standards, and comparison to the predicate device. A clinical investigation was performed in conformity with the requirements specified in Annex X of MDD93/42/EEC, and test for the comparison between SEZ Safety Syringe and the legally marketed predicate device was performed in accordance with "Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA". The results of the investigation showed that the SEZ Safety Syringe is clinically acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUL 0 8 2003

Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K031163
Trade/Device Name: SEZ Safety Intramuscular/Subcutaneous Syringes
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: April 2, 2003
Received: April 15, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K031163

Device Name: SEZ Safety Syringe

This device is a safety hypodermic syringe for intramuscular and subcutaneous injection of medication to patients. This device aids in prevention of needlestick injuries.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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